DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 7, 2015

Acclarent, Inc.
Mr. James Patrick Garvey II
Sr. Manager, Regulatory Affairs
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K150172
Trade/Device Name: Acclarent SE Inflation Device
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, And Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: March 12, 2015
Received: March 13, 2015

Dear Mr. Garvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150172

Device Name
ACCLARENT SE Inflation Device

Indications for Use *(Describe)*
The ACCLARENT® SE Inflation Device is an instrument intended to inflate, deflate and monitor pressure in balloon catheters used in sinus procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	James Patrick Garvey II Sr. Manager, Regulatory Affairs Phone: (650) 687-4807 Fax: (650) 687-4847
Date of Submission:	March 12, 2015
Device Trade Name:	ACCLARENT SE Inflation Device
Common Name:	Balloon Inflation Device
Device Classification:	Class I
Regulation Number:	21 CFR 874.4420
Classification Name:	Ear, nose, and throat manual surgical instrument
Product Code:	LRC
Predicate Devices:	Acclarent Balloon Inflation Device (K052198)
Device Description:	The ACCLARENT SE Inflation Device is an instrument intended to inflate, deflate and monitor pressure in balloon catheters used during sinus procedures. When used in a Balloon Sinuplasty dilation procedure, the inflation device enables the user to inflate the sinus balloon catheter, monitor the pressure within the balloon, and deflate the balloon. The device has a pressure gauge that indicates the atmospheric pressure at which the attached balloon is inflated, a high pressure syringe barrel that indicates the amount of fluid in the chamber, a mechanism to lock/unlock the piston, an ergonomic piston handle, and high pressure tubing used to attach the inflation device to the balloon catheters. The ACCLARENT SE Inflation Device should only be used with Acclarent Sinus Balloon Catheters with balloon sizes less than or equal to 7mmx24mm. Consult the individual Acclarent sinus balloon catheter carton labels for balloon size information.
Indications for Use:	The Acclarent® SE Inflation Device is an instrument intended to inflate, deflate and monitor pressure in balloon catheters used sinus procedures.

Technological Characteristics:

Attribute	Predicate Device Acclarent Balloon Inflation Device	Subject Device ACCLARENT SE Inflation Device
510(k) number	K052198	This Application
Model Number	BID30	SE Inflation Device
Rigidity	Rigid	Same
Pressure Gauge	Values Displayed in atmospheres (atm) & Pounds per Square in (PSI)	Values Displayed in atmospheres (atm) only
Length (Plunger not extended)	8.1”	8.8”
Length (Plunger extended)	11.3”	11.1”
Device Diameter (at hand position)	1.0 inch	1.3 inches
Flexible reinforced high pressure tubing	Yes	Same
Syringe capacity	20cc	7cc
Luminescent dial	Yes	Yes

Performance Data:

Bench testing met all acceptance criteria for attributes such as dimensional attributes, cycle fatigue, and reliability following three years of simulated accelerated aging.

Biocompatibility testing was performed for the ACCLARENT SE Inflation Device in accordance with EN ISO 10993-1: 2009. Biocompatibility testing for the SE Inflation Device included:

Test	Test Standard	Results
Intracutaneous Reactivity	ISO 10993-10:2013	Pass
Sensitization	ISO 10993-10:2013	Pass
In Vitro Cytotoxicity	ISO 10993-5:2009	Pass
Systemic Toxicity	ISO 10993-11:2009	Pass

Biocompatibility data indicates that the likelihood of a toxic biologic effect from the SE Inflation Device is negligible. Additionally, the ACCLARENT SE Inflation Device is determined to have met the requirements of EN ISO 10993-1 and FDA General Program Memorandum #G95-1, and is therefore considered safe from a biocompatibility perspective.

The sterilization process was validated per AAMI/ANSI/ISO 11135-1: 2007 and demonstrated a sterility assurance level of 10^{-6}. Testing of ethylene oxide residuals met ISO 10993-7:2008 requirements.

The subject device is not tested nor labeled as "non-pyrogenic". Packaging shelf life was established at three years via accelerated aging per ASTM F 1980-07. Clinical data was not necessary to establish the safety and efficacy

	of the ACCLARENT SE Inflation Device. The performance data demonstrates that the subject device performs as intended. The performance data demonstrate that the device performs as intended.
Summary of Substantial Equivalence:	The ACCLARENT SE Inflation Device is substantially equivalent to the predicate device.